

TAB 6

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

_____ x
THE CITY OF HUNTINGTON, : Civil Action
v. : No. 3:17-cv-01362
AMERISOURCEBERGEN DRUG :
CORPORATION, et al., :
Defendants. :
_____ x
CABELL COUNTY COMMISSION, : Civil Action
v. : No. 3:17-cv-01665
AMERISOURCEBERGEN DRUG :
CORPORATION, et al., :
Defendants. :
_____ x

BENCH TRIAL - VOLUME 26
BEFORE THE HONORABLE DAVID A. FABER, SENIOR STATUS JUDGE
UNITED STATES DISTRICT COURT
IN CHARLESTON, WEST VIRGINIA

JUNE 14, 2021

1 **A.** I hadn't remembered the Inciardi article and the
2 references that were in that introduction.

3 **Q.** Dr. Keyes, was that meant to be truthful when you gave
4 the answer?

5 **A.** It was meant to be truthful.

6 **Q.** Let me ask you, Dr. Keyes, a couple of preliminary
7 points around doctor prescribing activity. Doctors decide
8 on the dosage strength to include in a given prescription,
9 correct?

10 **A.** Can you say the question again?

11 **Q.** Sure. Doctors decide on the dosage strength to include
12 in a particular prescription, correct?

13 **A.** Yes.

14 **Q.** And also, doctors decide how many pills to include in a
15 given prescription for opioids, correct?

16 **A.** That's right.

17 **Q.** In other words, a doctor makes the judgment whether to
18 include a 10-day supply, a 30-day supply, or some other
19 duration for the prescription of the opioid, correct?

20 **A.** A doctor makes the decision about that, yes.

21 **Q.** And your view is that the overwhelming majority of
22 doctors prescribe opioids to their patients in good faith,
23 correct?

24 **A.** I don't know what proportion prescribe in good faith
25 but I would -- my opinion would be that it would be a

1 majority who make prescriptions based on the information
2 that they have.

3 **Q.** Well, let me ask it again just to be clear. Your view
4 is that the overwhelming majority of doctors prescribe
5 opioids to their patients in good faith, correct?

6 **A.** Yes. I -- I think that that is true. They base it on
7 the decision -- the information that they have.

8 **Q.** And starting in the late 1990s up through around 2010,
9 doctors increased their prescribing of opioids, correct?

10 **A.** Yes.

11 **Q.** And you wrote in your report at Page 23, if you want to
12 look at it, but I'll quote it to you. I think it will sound
13 familiar to you. "Pervasive over-prescribing resulted in
14 unused prescription opioid medicines diverted for monetary
15 value, bartered or for no cost among family and individuals
16 in a shared social network." Do you want me to point you to
17 that passage?

18 **A.** Yes, if you don't mind. I'm on Page 23.

19 **Q.** Yes. So, it's at Page 23 of your report. Let me see
20 if I can find it. It's in the middle of the page, Dr.
21 Keyes. There's a -- there's a bolded sentence.

22 **A.** I -- yes. It's at the top of my Page 23. Maybe we
23 have different versions.

24 **Q.** Oh, yes. Yes. You're right. Absolutely. At the top,
25 the sentence that -- and there's a sentence that's bolded

1 and it says, "Pervasive over-prescribing resulted in unused
2 prescribed opioid medications diverted for monetary value,
3 bartered, or for no cost among family and individuals in a
4 shared social network." Do you see that?

5 **A.** I do.

6 **Q.** And that's a true statement, correct?

7 **A.** That's my read of the literature.

8 **Q.** And the reference there to diverted for money, barter,
9 or no cost, that's diversion after the pills have either
10 been prescribed or illegally trafficked into the community,
11 correct?

12 **A.** With regard to over-prescribing, that is specifically
13 focused on prescribing behavior. There's another section,
14 oversupply.

15 **Q.** So, your point is that there was a pervasive
16 over-prescribing that led to unused pills and then they went
17 from the people who were prescribed those pills to others,
18 either through barter, through money, or through giving them
19 away, correct?

20 **A.** That's one source of the oversupply.

21 **Q.** And you also state in just a few sentences down in this
22 same paragraph of your report that, "Available estimates
23 indicate that 90 percent of patients prescribed opioids
24 after surgery have unused medication, most of which is not
25 disposed of or stored safely." Do you see that?

1 **A.** I do.

2 **Q.** And that's a true statement, correct?

3 **A.** Yes.

4 **Q.** And that's based on your --

5 **A.** In the literature that I read.

6 **Q.** Yeah. And so, when you -- when you say in the
7 literature you've read, you're purporting to give an
8 accurate summary of the literature when you state this?

9 **A.** I'm purporting to, yes.

10 **Q.** And that's your best effort?

11 **A.** Yes. I always update, you know, my opinions and
12 information with new -- new information as I'm gathering it.
13 So, I just want to be clear that I'm basing my statement on
14 the literature as I've read it.

15 **Q.** But when you wrote your report you meant to be
16 accurately reflecting the literature as you know it at the
17 time?

18 **A.** I certainly did.

19 **Q.** And the point you're making here in this sentence about
20 available estimates indicate that 90 percent of patients are
21 prescribed opioids have unused medication after surgery, the
22 point you're making there is that even though there might be
23 an underlying legitimate need for the prescription opioid,
24 the doctor prescribes too many pills to meet the need,
25 correct?

1 **A.** It's not referring to the legitimacy of the need. It
2 is referring to the -- the -- that there were too many pills
3 prescribed but I'm not -- that these studies did not
4 ascertain the legitimacy of the prescription itself, only
5 that there were unused medications. So, it could also be
6 that the prescription wasn't needed and that there were
7 unused medications.

8 **Q.** You're aware that many times prescription opioids are
9 prescribed for people after surgery to deal with acute pain,
10 correct?

11 **A.** It depends on the type of surgery. The amount of
12 prescription opioids that are prescribed depends on what
13 surgery we're talking about. There's many different kinds
14 of surgery.

15 **Q.** My question was narrower and probably simpler than
16 that, which is you are aware that prescription opioids are
17 often prescribed for treatment of acute pain after surgery,
18 correct?

19 **A.** Again, I think that that's too broad of a statement.

20 **Q.** You're not aware of that?

21 **A.** I am aware that opioids can be prescribed after some
22 surgeries.

23 **Q.** And so, the point is, there may be a surgery where
24 prescription opioids are prescribed to deal with the pain
25 after surgery, but in your review of the literature, you

1 determine that in 90 percent of those cases there were
2 unused medicines left after the person used them for
3 treating pain?

4 **A.** That's right.

5 **Q.** And that's a judgment being made by the doctor about
6 how many pills to include in that prescription for the
7 surgery, treatment of the pain following surgery, correct?

8 **A.** That's right.

9 **Q.** And so, this could happen quite often, correct, that
10 there might a circumstance where a prescription is written
11 and a doctor writes too many pills for that given
12 prescription, correct?

13 **A.** Yes.

14 **Q.** And the physician, in the good faith exercise of
15 judgment, decides to prescribe an opioid to meet a
16 particular need for a particular kind of pain, correct?

17 **A.** Can you state the question again?

18 **Q.** Yes. So, you could have a circumstance, I take it
19 there's many circumstances where a doctor could make a
20 legitimate good faith decision to prescribe opioids to deal
21 with a particular kind of pain, correct?

22 **A.** As I've said before, the doctor is making a
23 determination based on their understanding of the risks and
24 benefits of a particular opioid prescribing, which itself
25 has changed over time. You know, certainly, the

1 recommendations for prescribing have changed quite a lot
2 over the last ten years. And so, I'm not arguing that there
3 are not doctors that are acting in, quote-unquote, "good
4 faith" to write, quote-unquote "legitimate prescriptions",
5 but that that -- these studies are not purporting to report
6 on the efficacy or legitimacy of a particular prescription.
7 That's a separate evidence base.

8 **Q.** But going back to what we established a few minutes
9 ago, your view is that the overwhelming majority of doctors
10 prescribe opioids in good faith, correct?

11 **A.** Yes. I think many doctors are doing their best.

12 **Q.** The overwhelming majority, correct?

13 **A.** Certainly, yes, the majority.

14 **Q.** The overwhelming majority, correct?

15 **A.** Yes.

16 **Q.** And then the doctor acting in good faith to prescribe
17 the opioid may provide for more pills in that prescription
18 than are needed to meet the need for which the pills are
19 being prescribed, correct?

20 **A.** That can happen, yes.

21 **Q.** And in that case, even though the doctor has decided
22 that the medical need is legitimate, the doctor has
23 prescribed more pills than are needed to meet the need,
24 correct?

25 **A.** The doctor has made a determination of a medical need

1 and has prescribed too many pills in that circumstance that
2 you're -- this hypothetical that you're offering.

3 **Q.** And so, at Page 23 of your report, again, the same
4 page, the same paragraph, actually, you state that, among
5 non-medical opioid users interviewed about where they obtain
6 their opioids, 50.5 percent report from a friend or
7 relative.

8 Do you see that? It's almost exactly in the middle of
9 that paragraph. It's the sentence that begins data from the
10 National Survey on Drug Use and Health.

11 **A.** Yes. 50.5 percent receive -- in that survey received
12 prescription opioids from a friend or family.

13 **Q.** So, let's just be clear on what that is. It's a survey
14 from the National -- from the organization called NSDUH,
15 which is the National Survey on Drug Use and Health,
16 correct?

17 **A.** That's the -- the name of the survey is NSDUH.

18 **Q.** And that's a government survey that's run --

19 **A.** Yes.

20 **Q.** -- periodically?

21 **A.** Annually.

22 **Q.** And in that survey the report is that 50.5 percent of
23 non-medical users of opioids stated that they obtained the
24 opioids from a friend or a relative, correct?

25 **A.** Among the respondents in that survey, yes.

1 **Q.** And your analysis in the report of this passage was
2 that quite a bit of that was the result of unused
3 medications after a particular prescription, correct?

4 **A.** My analysis included unused prescriptions. The
5 previous sentence uses that statistic in citing evidence for
6 the proposition that the expansion of opioid sales and
7 distribution served as a catalyst for the overall
8 availability and one consequence would be unused medication.

9 **Q.** So, you would have unused medication that would be a
10 ready source of diversion to others from family and friends,
11 correct?

12 **A.** That's one pathway, yes.

13 **Q.** You also state just a -- I think in the next sentence
14 that the NSDUH data showed -- oh, sorry. Let me go down two
15 sentences further. There's another sentence that reads,
16 "Data from the NSDUH show that 57 percent of non-medical
17 opioid users in 2007 obtained opioid -- opioids from family
18 or relative for free with another 9 percent reporting that a
19 friend or a relative for purchase was also a source of the
20 opioids."

21 Do you see that?

22 **A.** I do.

23 **Q.** So, and that's a true statement, correct?

24 **A.** That is. Well, sorry. It's like -- it's based on my
25 review of the literature or I guess my reading of those

1 statistics from the NSDUH.

2 **Q.** Right. So, you're accurately reporting what NSDUH
3 reported, correct?

4 **A.** Yes.

5 **Q.** And the point is, so that would add up to 66 percent of
6 non-medical users obtaining pills from friends or family in
7 2007, correct?

8 **A.** Not exactly. That -- the survey -- it was not a
9 mutually exclusive category. People could report all of the
10 sources they obtained opioids from, including a doctor,
11 friends and family, a drug dealer; and then friends and
12 family for free, friends and family for money.

13 So, it's not -- can't add them up. You know, there's
14 going to be overlap. Some people got them for free from
15 family or friends and then, later on, they bought them from
16 a friend. You know, so --

17 **Q.** I see. I see what you're saying. So, but the point
18 is, the survey reflected, again, that more than half of the
19 people who were non-medical users, in other words, people
20 who are using opioids without a prescription, more than half
21 reported they had obtained the opioids from a friend or
22 relative for free, correct?

23 **A.** That's true, but that's not the -- that might not be
24 the only source. But that is a source. It's a -- it's a
25 very common source for opioids.

1 **Q.** So, fair enough. So, somebody who is a non-medical
2 opioid user might get some for free from family, but then
3 might also go out on the street and buy some more, correct?

4 **A.** Well, I think more germane to the discussion, most
5 non-medical users also obtain opioids medically. So,
6 there's a large overlap between those two. They're not
7 distinct. You don't have one group of legitimate opioid
8 users and one group of non-medical users. There is a lot of
9 overlap between those two groups.

10 **Q.** But you would have -- you could have a circumstance
11 where somebody is a non-medical user, they might have a
12 prescription for some, but then they obtain other pills from
13 family or friends for free, correct?

14 **A.** That's right.

15 **Q.** Or you could have a circumstance where somebody has a
16 prescription for opioids, but they also go out and buy
17 opioids on the street, correct?

18 **A.** That is a -- that is a scenario that occurs.

19 **Q.** And they're non-medical users, so they -- by
20 definition, they are using opioids for some non-medical
21 purpose, correct?

22 **A.** That's right.

23 **Q.** And your view is that the high volume of opioid
24 prescriptions that doctors were writing became the
25 foundation for the overall expansion of the opioid supply,

1 correct?

2 **A.** Can you say that sentence again?

3 **Q.** Yes. Your view is that the high volume of opioid
4 prescriptions that doctors were writing became the
5 foundation for the overall expansion of the opioid supply,
6 correct?

7 **A.** That is a major source of the foundation, yes.

8 **Q.** And, in your view, it is -- it was a principal
9 foundation of the expansion of the supply of opioids,
10 correct, the prescribing by doctors?

11 **A.** I think it's a major foundation of the increases in
12 prescribing and, you know, what we saw subsequently with the
13 heroin epidemic.

14 **Q.** And your view is that the high volume of opioid
15 prescriptions also became the foundation for the overall
16 expansion and opioid-related harm, correct?

17 **A.** The high volume of prescribing was a foundational
18 source of the epidemic that followed, including our current
19 fentanyl epidemic.

20 **Q.** And it was the foundation for the overall expansion and
21 opioid-related harm, correct?

22 **A.** Yes. It was a principal source. I would say there's
23 other sources. You know, it's a -- in these epidemics where
24 you have a lot of different underlying and interacting
25 factors, certainly, the pervasive over-prescribing was one

1 of the foundational ones.

2 **Q.** And one of the foundational ones in particular for the
3 expansion of opioid-related harm was the level of
4 prescribing by doctors, correct?

5 **A.** The level of prescribing by doctors certainly
6 contributed to the availability of opioids in the community.
7 So, I would say that that is a true statement, but it is not
8 exclusive of other sources of prescription opioids, as I've
9 outlined and we've discussed.

10 **Q.** But let me -- let me be clear on it. Just let me ask
11 it one more time. You agree that the high volume of opioid
12 prescriptions became the foundation for the overall
13 expansion in the opioid supply and opioid-related harm,
14 correct?

15 **A.** Yes. I believe I've written that before, but in
16 context, I would just say it's a foundation.

17 **Q.** Yes. So, your answer is yes to my question?

18 **A.** Yes.

19 **Q.** And then, your view is that the opioid crisis would not
20 have occurred if prescribing opioids had not become standard
21 practice in managing acute and chronic pain, correct?

22 **A.** That's right.

23 **Q.** Distributors did not ship more pills than doctors
24 prescribed, correct?

25 **A.** I haven't evaluated the distributor shipments, so I

1 wouldn't want to comment on them. I don't have an opinion
2 on that.

3 **Q.** You're aware, I take it, that no matter how many
4 opioids a distributor ships to a given pharmacy, if there's
5 not a prescription from a doctor, those opioids stay on the
6 pharmacy shelf and never reach the community, correct?

7 **A.** My understanding generally is that that's how it's
8 supposed to work. I don't know exactly how it worked in
9 every circumstance here.

10 **Q.** Well, let me ask it again just to make clear. No
11 matter how many opioids a distributor ships to a given
12 pharmacy, if there's not a prescription from a doctor, those
13 opioids are supposed to stay in the pharmacy and not go out
14 to the public, correct?

15 **A.** They certainly are supposed to.

16 **Q.** And so, you -- the answer is yes?

17 **A.** Yes.

18 **Q.** You published an article in 2013 that said, "The data
19 are robust in demonstrating that rates of overdoses are
20 proportional to the rates of prescribing", correct?

21 **A.** Which article is this?

22 **Q.** I'm not sure if I have that article right handy. Do
23 you remember publishing such an article that said that, "The
24 data are robust in demonstrating that rates of overdoses are
25 proportional to the rates of prescribing"?

1 **Q.** And so then, in addition to those 20, there's another
2 45 deaths that you attribute indirectly to prescription
3 opioids?

4 **A.** Yes.

5 **Q.** Based on the methodology we discussed a few minutes
6 ago; is that right?

7 **A.** That's right.

8 **Q.** And so, from the 105 total deaths, total opioid-related
9 overdose deaths in 2018, we're left with, I believe, it's 40
10 deaths that you don't attribute either directly or
11 indirectly to prescription opioids, correct?

12 **A.** Just about, yeah.

13 **Q.** So, that means you have a -- you have a 40 percent or
14 so of the 105 total opioid-related overdose deaths you don't
15 attribute to prescription opioids, correct?

16 **A.** That's right.

17 **Q.** Either directly or indirectly, correct?

18 **A.** Yes.

19 **Q.** Did you say yes? I'm sorry.

20 **A.** Yes.

21 THE COURT: We need to pull the plug here, Mr.
22 Hester, when you get to a convenient stopping place.

23 MR. HESTER: All right. This is -- this is as
24 good a time as any, Your Honor.

25 THE COURT: All right. We'll come back at 2:00

1 and you can get up and walk around or do whatever you want
2 to do for two hours, Dr. Keyes.

3 THE WITNESS: Thank you.

4 (Recess taken)

5 THE COURT: Is Dr. Keyes in the courtroom?

6 Okay, Mr. Hester, you may continue, sir.

7 MR. HESTER: Thank you, Your Honor.

8 BY MR. HESTER:

9 **Q.** Good afternoon Dr. Keyes.

10 **A.** Good afternoon.

11 **Q.** Earlier today, you made a reference to pill mills; do
12 you recall that?

13 **A.** Yes.

14 **Q.** And I wanted to ask you in your report that you
15 submitted, your expert report that you submitted in the MDL
16 litigation, you stated that, quote, "Pill mills do not
17 explain in any significant way the expansion of opioid
18 prescribing and opioid-related harm in the U. S."

19 Do you recall saying that in your MDL report?

20 **A.** I do.

21 **Q.** And that's a true statement, correct?

22 **A.** Yes.

23 **Q.** Let me turn now to your estimate of the OUD population
24 in Huntington and Cabell County. And I'm going to do a
25 little bit on the board here.

1 And your view, Dr. Keyes, is that there is no
2 systematic way to count the OUD population, correct?

3 **A.** That's right.

4 **Q.** And so, because you can't actually count the OUD
5 population, you developed an estimate for it, correct?

6 **A.** Yes.

7 **Q.** And to estimate it, you divided the number of overdose
8 -- overdose deaths due to drugs in Cabell-Huntington in 2018
9 by a mortality rate; is that right?

10 **A.** By two mortality rates.

11 **Q.** Right. So, I will get into that.

12 **A.** Okay.

13 **Q.** And maybe we'll start with the simpler point first.

14 You -- you refer to a methodology that you described as
15 a multiplier method, right?

16 **A.** Yes.

17 **Q.** And if I can write this formula over here, I will ask
18 you, Dr. Keyes, so we're talking the same language, I hope.
19 So, the basic principle of the multiplier method is that if
20 you know the number of deaths due to drug overdose and you
21 know the mortality rate associated with a population of drug
22 users, you can back into the OUD number; is that right?

23 **A.** That's the basic idea.

24 **Q.** So, another way to put that based on the formula I put
25 up there, you could also multiply OUD, the OUD population,